REMARKS

Claims 1, 3, 10-17 and 19-28 are pending in the application. Claim 10 (which is withdrawn) has been amended to correct a dependency from Claim 6 (a canceled claim) to Claim 1. This amendment does not add any new matter. Thus, Claims 1, 3, 17, 19, 21-23, 25, 27 and 28 are presently under examination.

Previous Claim Objection Withdrawn

Applicant notes with thanks that the previous Claim objections have been withdrawn.

New Claim Objection

Claim 10 is objected to because of its dependency on withdrawn Claim 6. The dependency of Claim 10 has now been changed to Claim 1 and this objection should be withdrawn.

Rejection Under 35 U.S.C. §103(a) Based on WEBER

The Examiner has rejected Claims 1, 17, 19, 21-23, 25, 27 and 28 under 35 U.S.C. §103(a) over Weber, WO2003/026532 ("WEBER"). This rejection is respectfully traversed.

WEBER describes its technology as including a matrix material as follows:

> . . . a matrix material according to the invention may be any material suitable, or later determined to be suitable, for use in such a medical device. The matrix material may be any material that is historically or currently utilized, or contemplated for future use, in a corresponding medical device not comprising a nanocomposite component. The matrix material may be comprised of organic, inorganic or hybrid organic/inorganic materials. Additionally, the matrix material may be a single material or a combination of materials, e.g., the matrix material may be a metal alloy, copolymer or polymer blend.
>
> Exemplary matrix materials include, for example, polymers, such as thermoplastics and thermosets. Examples thermoplastics suitable for use as a matrix material include, for example polyolefins, polyamides, polyesters, polyethers, polyurethanes, polyureas, polyvinyls, polyacrylics, fluoropolymers, copolymers and block copolymers thereof, and mixtures thereof. Representative examples of thermosets that may be utilized as a matrix material include elastomers [sic, elastomers] such as EPDM, epichlorohydrin, nitrile butadiene elastomers, silicones, etc. Conventional thermosets such as expoxies, isocyanates, etc. , can also be used. Biocompatible thermosets may also be used and these

include, for example, biodegradable polycaprolactone, poly (dimethylsiloxane) containing polyurethanes and ureas, and polysiloxanes.

(Page 7, line 29 - page 8, line 15)

WEBER does not render the currently claimed invention unpatentable under 35 USC 103(a), particularly an implantable or insertable medical device comprising a release region, said release region comprising (a) a polymeric carrier comprising a hydrophobic first polymer and (b) drug loaded nanoparticles dispersed within said polymeric carrier, said drug loaded nanoparticles comprising: silicate particles comprising a layered silicate material; a hydrophilic first therapeutic agent; and a hydrophilic second polymer, wherein the first therapeutic agent ***and*** hydrophilic second polymer are structurally associated with the silicate particles in that the first therapeutic agent and hydrophilic second polymer occupy spaces between adjacent layers of the silicate material of each silicate particle to form a depot for the first therapeutic agent.

The Examiner responds that WEBER teaches a polymer blend and that this description can be used to meet the hydrophobic and hydrophilic elements of the claimed invention. This is merely hindsight reconstruction using the present invention as a roadmap. (See Office Action, page 3).

Moreover, WEBER does not describe that the first therapeutic agent ***and*** the hydrophilic second polymer occupy spaces between ***adjacent*** layers of the silicate material of each silicate particle to form a depot for the first therapeutic agent. The Examiner agrees that WEBER "does not explicitly disclose the placement of the therapeutic agent in the spaces between adjacent layer of the silicate material of each silicate material to form a depot." (Office Action, page 5). However, the Examiner goes on to say that since WEBER "teaches nanoparticles made of the same material being instantly claimed . . . [t]he placement of hydrophilic therapeutic agent in the spaces between the adjacent layers of the silicate material is a property of interaction between the silicate and the therapeutic agent." (Office Action, page 5). It is noted, however, that in addition to the therapeutic agent, the hydrophilic second polymer also occupies the spaces between the adjacent layers of the silicate material of each silicate particle in the claims. The Examiner has failed to address the hydrophilic second polymer. To the extent that the Examiner is suggesting that ***both*** the therapeutic agent and the hydrophilic second polymer would inherently occupy the

spaces between the adjacent layers of the silicate material, the examiner has not set forth reasons why this necessarily the case. In this regard, see MPEP 2112 IV:

> The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) …

For at least the preceding reasons, claims 1, 17, 19, 21-23, 25, 27 and 28 are patentable over WEBER I.

Rejection Under 35 U.S.C. § 103(a) Based on WEBER in View of WEBER II

The Examiner has rejected Claims 1 and 3 under 35 U.S.C. §103(a) based on WEBER in view of Weber et al. U.S. Patent No. 6,743,463 ("WEBER II"). This rejection is respectfully traversed for the reasons described above for WEBER and also for the following reasons.

Claims 1 and 3 are patentable over WEBER II for at least the reasons set forth in the preceding section. WEBER II, which is cited for its disclosure of halofuginone as a therapeutic agent, does not make up for the deficiencies in WEBER.

For at least the preceding reasons, withdrawal of the outstanding rejection under 35 USC 103(a) is respectfully requested.

CONCLUSION

Applicants submit Claims 1, 3, 17, 19, 21-23, 25, 27 and 28 are in condition for allowance. Reconsideration is requested and an early notice of allowance is earnestly solicited. Entry of this Amendment and Response is respectfully requested as it will put the case in a form for allowance or in better form for an appeal. It is believed that this Amendment and Response is being submitted in time for an Advisory Action should the Examiner require further changes to the Claims. Should the Examiner be of the view that an interview would expedite consideration of this Response or of the application at large, the Examiner is requested to telephone the Applicant's attorney at the number listed below in order to resolve any outstanding issues in this case.

Respectfully submitted,

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